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ORIGINAL PAPER

Drug-eluting versus bare-metal stents in ST-segment elevation myocardial infarction: a mortality analysis from the EUROTRANSFER Registry

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Abstract
Aim To assess the patterns of drug-eluting stent (DES) and bare-metal stent (BMS) implantation and associated real-life outcomes in patients with ST-segment elevation myocardial infarction (STEMI) transferred for primary percutaneous coronary intervention (PCI).
Methods Data were gathered for 1,650 consecutive STEMI patients transferred for primary PCI from hospital networks in seven countries of Europe from November 2005 to January 2007. We identified 1,428 patients with $\geq$1 stent implanted (86.5%). DES were implanted in 382 patients (26.8%) and BMS in 1,046 patients (73.2%) of 1,428 who received stent.
Results High variability in DES use among countries participating in the registry (range from 6.8 to 72.1%) was observed. The use of DES in STEMI declined during the fourth quarter of 2006 through the first quarter of 2007. In the assessed population, age, previous PCI, systolic and diastolic pressures on admission, clopidogrel before admission, left anterior descending artery as the infarct-related artery, and thrombus aspiration device use were identified as the independent predictors of DES implantation. Use of DES was associated with significantly lower rates of ischemic events during follow-up (1-year mortality: BMS vs. DES: 6.7% vs. 3.1%; $p = 0.014$), but observed difference was no longer significant after adjustment for propensity score (adjusted OR (95% CI): 0.55 (0.28–1.06); $p = 0.07$).
Conclusions In this large, prospective European registry, the presence of large geographical and temporal variation of DES utilization in STEMI in Europe was confirmed. DES in STEMI appear to be as safe as BMS, with similar mortality after adjustment for potential confounders and trend toward lower 1-year mortality in patients treated with DES.

Keywords Myocardial infarction · Angioplasty · Stent · Drug-eluting stent · Bare-metal stent · Registries

Background

Recently, large multicenter studies [1–3] and two meta-analyses of randomized trials [4, 5] have confirmed that drug-eluting stents (DES) implantation during primary percutaneous coronary intervention (PCI) in ST-segment elevation myocardial infarction (STEMI) reduces the risk of target-vessel revascularization compared with bare-metal stent (BMS) use. Importantly, DES application in these studies was not associated with elevated risk of death, stent thrombosis and recurrent myocardial infarction [1–5]. On the other hand, unrestricted implantation of DES in acute coronary syndrome setting was identified as an independent predictor of stent thrombosis [6–8]. Still, data drawn from large, unselected cohorts of STEMI patients treated with primary PCI may be helpful to confirm the safety of DES use in such clinical scenarios.

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The present study assesses the patterns of DES and BMS implantation and associated real-life outcomes in patients with STEMI transferred for primary PCI, based on data from the EUROTRANSFER (European Registry on Patients with ST-Elevation MI Transferred for Mechanical Reperfusion with a Special Focus on Upstream Use of Abciximab) Registry [9–11].

Methods

Study population

The EUROTRANSFER Registry (ClinicalTrials.gov number NCT00378391) design and main results have been previously published [9–11]. In this registry, data concerning 1,650 transferred STEMI patients in 15 STEMI hospital networks from seven European countries between November 2005 and January 2007 were collected. For the purpose of the present analysis, data of 1,428 (86.5%) registry patients who underwent immediate PCI with implantation of $\geq$1 stent were assessed. Patients were classified based on stent type used during primary PCI. The BMS group consisted of patients in whom only BMS stents were implanted. The DES group included patients with $\geq$1 DES implanted. Patients with multiple stents implanted of both types were included in the DES group. The study protocol and execution complied with the Declaration of Helsinki and was approved by the Jagiellonian University Bioethics Committee in Krakow, Poland.

Clinical assessment

The primary objective of the present analysis was the assessment of 1-year all-cause mortality. Additionally, rates of all-cause death, nonfatal reinfarction, urgent revascularization (PCI or coronary artery bypass grafting), puncture site hematoma, intracranial hemorrhage and major bleeding requiring transfusion at 30 days after primary PCI were assessed [9, 10]. Thrombolysis in myocardial infarction (TIMI) flow in the infarct-related artery before and after primary PCI, ST-segment resolution after PCI and rate of angiographic PCI complications (no-reflow, distal embolization) were also assessed at the investigator's discretion.

Statistical analysis

Data were analyzed according to the established standards of descriptive statistics. Results were presented as numbers (percentages) of patients or medians (inter-quartile range) where applicable. Differences between groups stratified by stent type were tested using chi-square test and Fisher's exact test for dichotomous variables and the Mann–Whitney *U* test for continuous variables. The difference in death rates between groups during the follow-up period was assessed by the Kaplan–Meier method using the log-rank test. Additionally, multivariable logistic regression analysis was performed to find independent predictors of DES use. Following covariates were tested: sex, age, body mass index, past medical history (previous myocardial infarction, renal insufficiency, previous heart failure symptoms, previous PCI, previous coronary artery bypass grafting, previous stroke, smoking status, diabetes mellitus, peripheral arterial disease), medications before admission (clopidogrel, abciximab, thrombolysis before PCI hospital), status on admission (heart rate, systolic blood pressure, diastolic blood pressure, heart rate, Killip class), time from chest pain onset to diagnosis, time from diagnosis to balloon inflation, infarct-related artery, presence of multivessel disease, TIMI flow before PCI, and thrombus aspiration devices use. Results were presented as odds ratios (OR) with 95% confidence intervals (CI). To adjust for possible selection bias, propensity score [12] was calculated based on the above-mentioned factors tested in the multivariable model. Differences in clinical outcomes between patients treated with BMS and DES were adjusted for propensity score using logistic regression analysis and presented as adjusted OR with 95% CI. All tests were two tailed and a p value of <0.05 was considered to be statistically significant. All statistical analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, IL).

Results

A total of 1,428 patients with $\geq$1 stent implanted during primary PCI were identified in the EUROTRANSFER Registry database. At the discretion of operators, $\geq$1 DES was implanted in 382 patients (26.8%, DES group) and BMS without any DES in 1,046 patients (73.2%, BMS group) of the 1,428 who received stent. As shown in Table 1, patients treated with DES were younger and had higher rate of previous PCI and shorter times from the symptoms onset to diagnosis. Additionally, they were more likely to receive upfront abciximab. In contrast, clopidogrel before admission to PCI hospital was less frequently used in the DES group (Table 1). Data concerning interventional treatment are summarized in Table 2. The left anterior descending artery was identified as the infarct-related artery more frequently in patients with DES. In patients treated with DES, the overall number of stents implanted during index primary PCI was higher than in patients with BMS only. Also, thrombus aspiration, as well as direct stenting technique, was less frequently applied in patients receiving DES.

Table 1 Baseline demographics, treatment before admission and clinical status on admission to percutaneous coronary intervention center according to stent type

Variable	BMS ($n = 1046$)	DES ($n = 382$)	p value
Age (years)	65 (55–74)	62 (52–70)	<0.001
Age ≥65 years	532 (50.9%)	168 (44.0%)	0.023
Men	754 (72.1%)	300 (78.5%)	0.014
Body mass index (kg/m^2)	26.6 (24.1–29.4)	26.5 (24.2–29.4)	0.63
Diabetes mellitus	153 (14.6%)	63 (16.5%)	0.40
Insulin	53 (5.1%)	15 (3.9%)	0.40
Previous myocardial infarction	110 (10.5%)	44 (11.5%)	0.63
Previous heart failure symptoms	11 (1.1%)	5 (1.3%)	0.78
Previous percutaneous coronary intervention	41 (3.9%)	40 (10.5%)	<0.001
Previous coronary artery bypass grafting	14 (1.3%)	5 (1.3%)	0.99
Current smoker	389 (37.2%)	150 (39.3%)	0.50
Peripheral arterial disease	28 (2.7%)	12 (3.1%)	0.72
Previous stroke	40 (3.8%)	8 (2.1%)	0.14
Chronic renal failure	23 (2.2%)	7 (1.8%)	0.69
Time from symptoms onset to diagnosis (min)	115 (60–225)	85 (51–173)	<0.001
Aspirin before cathlab	992 (94.8%)	352 (92.1%)	0.058
Clopidogrel before cathlab	429 (41.0%)	49 (12.8%)	<0.001
Unfractionated heparin before cathlab	706 (67.5%)	279 (73.0%)	0.045
Abciximab before cathlab	437 (41.8%)	200 (52.4%)	<0.001
Thrombolysis before cathlab	52 (5.0%)	17 (4.5%)	0.78
Heart rate on admission (beat/min)	78 (67–90)	77 (68–86)	0.29
Systolic blood pressure on admission (mmHg)	133 (117–154)	130 (115–149)	0.018
Diastolic blood pressure on admission (mmHg)	80 (70–90)	80 (67–90)	0.003
Killip class on admission			
I	849 (81.2%)	330 (86.3%)	<0.001
II	150 (14.3%)	26 (6.8%)	
III	20 (1.9%)	11 (2.9%)	
IV	27 (2.6%)	15 (3.9%)	

Values are presented as numbers (percentages) or medians (inter-quartile range)

BMS bare-metal stent; *DES* drug-eluting stent

High variability in DES use among countries participating in the registry (range from 6.8 to 72.1%) was observed (Fig. 1a). Similarly, frequency of DES implantation varied in different time periods of the registry (Fig. 1b). Age, previous PCI, systolic and diastolic pressures on admission, clopidogrel before admission, left anterior descending artery as the infarct-related artery and thrombus aspiration device use were identified as the independent predictors of DES implantation (Table 3).

The rates of final TIMI grade 3 flow after PCI, as well as angiographic complications frequency, were similar in the both groups (Table 2). Also, there was no difference in the rate of ST-segment resolution >50% after PCI between groups (BMS vs. DES; 79.0 vs. 76.2%; $p = 0.26$). As summarized in Table 4, patients treated with DES were at lower risk of ischemic events during the 30-day follow-up. Also, 1-year mortality was significantly lower in patients receiving DES. However, these differences in mortality were no longer significant after adjustment for propensity score (Table 4). The Kaplan–Meier curves for 1-year survival according to stent type are shown in Fig. 2. One-year mortality in patients stratified by stent type for different countries and enrollment time periods is shown in Fig. 1.

Discussion

In our study, the frequency of DES implantation in STEMI setting was similar to that observed in large multicenter GRACE Registry [13]. Also, similarly to previous reports, we confirmed large international geographical variation in DES utilization in networks of STEMI treatment [13, 14]. Importantly, DES were preferably implanted, at the discretion of operators, in the lower risk individuals [13, 14]. We hypothesized that the observed difference in the frequency of upstream use of abciximab and/or clopidogrel, as well as thrombus aspiration device use in patients treated with DES versus BMS, may be a marker of differences between participating centers in the treatment logistic of STEMI and primary PCI technique. On the other hand, there is also possibility that DES were preferably implanted

Table 2 Invasive treatment details according to stent type

Variable	BMS (n = 1046)	DES (n = 382)	p value
Femoral access	900 (86.0%)	336 (88.0%)	0.38
LAD as infarct-related artery	452 (43.2%)	190 (49.7%)	0.031
Multi-vessel disease	528 (50.5%)	194 (50.9%)	0.91
Intra-aortic balloon pumping	37 (3.5%)	15 (3.9%)	0.75
Time from symptoms onset to PCI (min)	240 (164–380)	201 (142–288)	<0.001
TIMI grade 2–3 flow before PCI	308 (29.4%)	109 (28.5%)	0.74
Number of stents			
1	860 (82.2%)	262 (68.6%)	<0.001
2	149 (14.2%)	87 (22.8%)	
3	31 (3.0%)	25 (6.5%)	
≥4	6 (0.6%)	8 (2.1%)	
Thrombus aspiration	142 (13.6%)	22 (5.8%)	<0.001
Direct stenting	223 (21.3%)	56 (14.7%)	0.005
Non-infarct-related artery PCI	46 (4.4%)	17 (4.5%)	0.99
TIMI grade 3 flow after PCI	956 (91.4%)	358 (93.7%)	0.19
Angiographic PCI complications			
No reflow	35 (3.3%)	9 (2.4%)	0.39
Distal embolization	22 (2.1%)	4 (1.0%)	0.26

Values are presented as numbers (percentages) or medians (inter-quartile range)

BMS bare-metal stent; *DES* drug-eluting stent; *LAD* left anterior descending artery; *PCI* percutaneous coronary intervention; *TIMI* thrombolysis in myocardial infarction

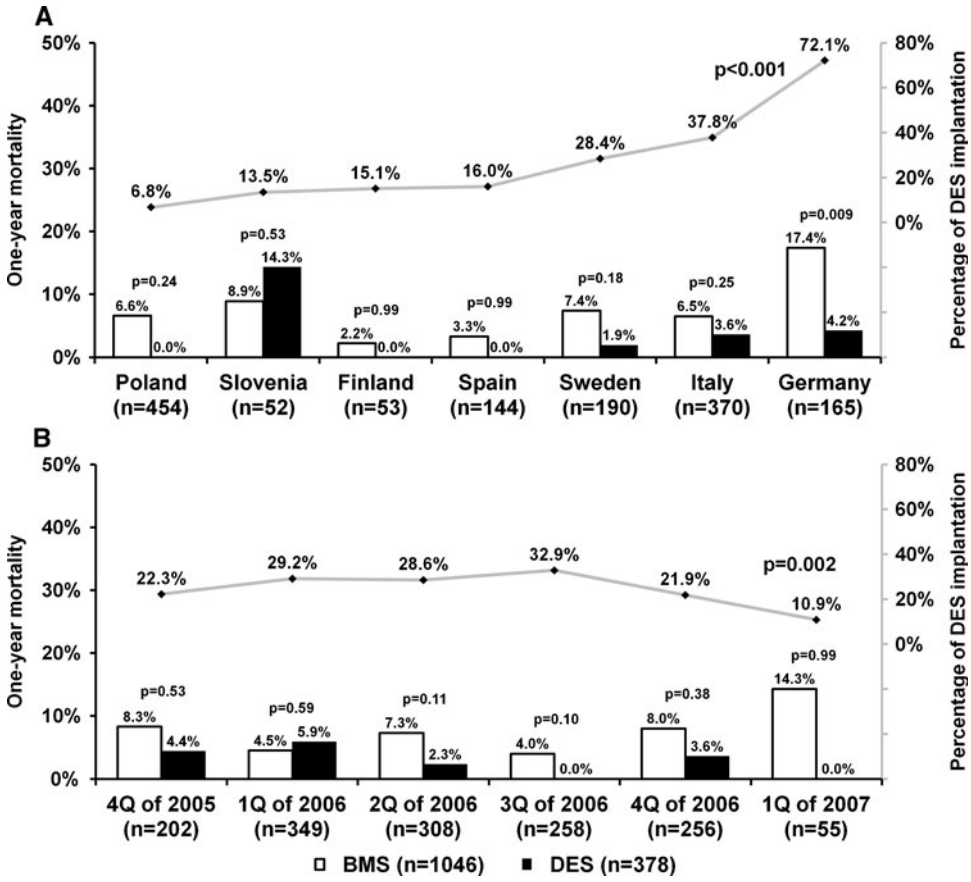

Fig. 1 One-year mortality in patients treated with bare-metal stent (BMS, *empty bars*) and drug-eluting stent (DES, *solid bars*), and frequency of DES use (*gray line*) stratified by country (**a**) and enrollment time periods (**b**)

in patients with early reperfusion induced by upstream antiplatelet therapy, as the presence of infarct-related artery patency with low thrombus load before DES implantation was shown to be associated with lower risk of stent thrombosis during follow-up, in comparison to large thrombus burden [15].

Table 3 Predictors of drug-eluting versus bare-metal stent use

Variable	OR	95% CI	*p* value
Age (per 1 year)	0.97	0.96–0.98	<0.001
Previous PCI	2.97	1.78–4.95	<0.001
Systolic blood pressure on admission (per 1 mmHg)	1.01	1.00–1.02	0.042
Diastolic blood pressure on admission (per 1 mmHg)	0.98	0.96–0.99	<0.001
Clopidogrel before PCI hospital	0.21	0.15–0.29	<0.001
Left anterior descending artery as IRA	1.37	1.05–1.78	0.019
Thrombus aspiration device use	0.32	0.20–0.54	<0.001

Values are presented as odds ratio with 95% confidence interval

CI confidence interval; *IRA* infarct-related artery; *OR* odds ratio; *PCI* percutaneous coronary intervention

During the 1st year of the registry time period, we observed a gradual increase of frequency of DES implantation in STEMI patients. Then, the use of DES declined during the fourth quarter of 2006 through the first quarter of 2007. Similar temporal changes in frequency of DES implantation in STEMI [13], as well as non-ST-segment elevation acute coronary syndromes [16] were reported from the large, multicenter registries. This decrease of DES use was related probably to the public debate about the risks of DES, which was started after the European Society of Cardiology Congress in Barcelona 2006, where data suggesting an increased risk of stent thrombosis, myocardial infarction and myocardial infarction/death in patients treated with first generation of DES during long-term follow-up were reported [17]. Importantly, these safety concerns were not confirmed by more recent analysis of data from the SCAAR registry [18], as well as other studies [1–5]. Due to positive results of recent studies, an increase in DES utilization, also in acute coronary syndromes, has been observed [16].

Observed difference in baseline risk of the patients may be the main reason of more favorable outcomes (lower unadjusted mortality) of the DES group, as this difference in mortality was no longer significant after adjustment for potential confounders. These observations are also supported by results of recently published studies [1–5]. Our study was too small to properly assess the differences in 1-year mortality between DES versus BMS patients from each country, as well as those treated in different registry time periods. However, absolute values for mortality were in favor of DES implantation in the majority of analyzed subgroups.

Limitations of the study

The main limitation of the study is non-randomized nature and the potential of selection bias. Even with the use of propensity score adjustment, we were unable to control all patients, operator and center-related factors influencing the association between DES implantation and patients' outcomes. Also, data concerning DES type, as well as stent size and length, were not collected. Analyzed 1-year outcomes were limited to mortality only, and important data concerning nonfatal reinfarction and stent thrombosis were

Table 4 Clinical outcomes according to stent type

Variable	BMS ($n = 1046$)	DES ($n = 382$)	*p* value	Adjusted OR (95% CI)	Adjusted *p* value
30-day					
Death	50 (4.8%)	7 (1.8%)	0.014	0.46 (0.20–1.06)	0.07
Death + nonfatal reinfarction	67 (6.4%)	13 (3.4%)	0.037	0.53 (0.28–1.00)	0.05
Death + nonfatal reinfarction + urgent revascularization	75 (7.2%)	15 (3.9%)	0.026	0.54 (0.30–0.99)	0.047
Major bleeding requiring transfusion	16 (1.5%)	5 (1.3%)	0.81	0.55 (0.17–1.76)	0.31
Intracranial hemorrhage	0 (0.0%)	0 (0.0%)	–	–	–
Puncture site hematoma	49 (4.7%)	31 (8.1%)	0.014	1.48 (0.90–2.44)	0.13
All bleeding	62 (5.9%)	35 (9.2%)	0.33	1.26 (0.79–2.02)	0.33
Death + nonfatal reinfarction + major bleeding requiring transfusion	78 (7.5%)	18 (4.7%)	0.07	0.57 (0.32–1.01)	0.05
1-year					
Death	70 (6.7%)	12 (3.1%)	0.014	0.55 (0.28–1.06)	0.07

Values are presented as numbers (percentages) and as odds ratios adjusted for propensity score with 95% confidence intervals

BMS bare-metal stent; *CI* confidence interval; *DES* drug-eluting stent; *OR* odds ratio

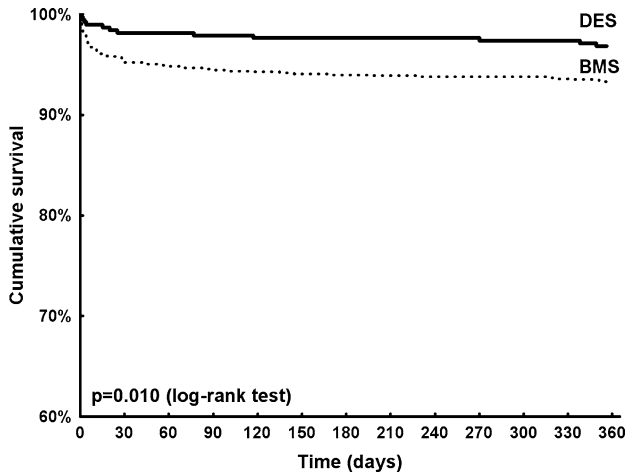

Fig. 2 Kaplan–Meier survival *curves* for patients treated with bare-metal stent (BMS, *dotted line*) and drug-eluting stent (DES, *solid line*)

missing. We were also unable to assess the compliance with dual antiplatelet therapy during the follow-up period. Also, frequency of DES utilization in the centers participating in the EUROTRANSFER Registry may not reflect the frequency of DES implantation in the overall country. The interpretation of the TIMI flow, as well as post-PCI ST-segment resolution, was limited by the fact that these represent not independent core laboratory, but physicians' assessments. On the other hand, this large multinational registry reflects real-life treatment patterns performed in the setting of STEMI networks.

Conclusions

In this large, prospective European registry, presence of large geographical and temporal variation of DES utilization in STEMI in Europe was confirmed. DES in STEMI appear to be as safe as BMS, with similar mortality after adjustment for potential confounders and trend toward lower 1-year mortality in patients treated with DES.

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